

WHAT IS CLAIMED IS:

Sub
B1
E1

1. A device for marking tissue within a human body to identify a selected location for a diagnostic or therapeutic procedure, comprising:
 a marker element; and
 an apparatus for remotely delivering said marker element from outside the human body to the selected tissue location, using an aided visualization device; wherein said marker element becomes implanted in said selected tissue location.

2. A device as recited in claim 1, wherein said apparatus includes a member having a distal region and a proximal region, said member being adapted to extend through said human body, wherein said distal region is adapted to retain and deploy said marker element and said proximal region is linked to said distal region, so that predetermined marker deployment functions may be communicated from said proximal region to said distal region.

3. A device as recited in claim 2, wherein said apparatus comprises a distal region which is adapted to pierce said human body.

4. A device as recited in claim 2, wherein said marker element may travel along said ³⁸member from said proximal region to said distal region for deployment therefrom.

5. A device as recited in claim 2, wherein said distal region includes a forming die, which is adapted to form said marker element into a predetermined shape as the marker element is deployed from said member.

25

25
E 6. A device as recited in claim ~~5~~²⁵, wherein said ~~predetermined~~^{desired} shape is substantially helical.

7. A device as recited in claim 4, wherein said member comprises a tube having a lumen extending axially therethrough, the proximal region of the tube being adapted to receive said marker element so that it may travel axially through said lumen to the distal region of the tube.

8. A device as recited in claim 7, wherein said apparatus is adapted to draw a vacuum through said tube.

B 9. A device as recited in claim ~~7~~³⁸, wherein said apparatus further comprises a mandrel which is adapted to push said marker element through said tube lumen.

B 10. A device as recited in claim ~~7~~³⁸, wherein said marker element comprises a pre-formed spring having a predetermined shape which is compressed into said tube lumen, and is adapted to expand upon deployment from said distal region, such that the expansion of the spring implants the marker element into the tissue at said selected tissue location.

5

11. A device as recited in claim 10, wherein said marker element further comprises a plurality of attachment members, said attachment members each being adapted to expand when the marker element is released from said tube lumen, such that each attachment member expands with sufficient energy to embed itself into the tissue at the selected tissue location, thereby implanting the marker element.

5

12. A device as recited in claim 10, wherein said marker element is

deployed within tissue at said selected tissue location, the marker element being adapted to expand sufficiently that the edges thereof press against said tissue to implant the marker element.

13. A device as recited in claim 2, wherein said member is adapted to receive a deployment actuator connector which extends axially therealong, said connector comprising a distal portion which extends distally of the member and a proximal portion which extends proximally of the member, said proximal portion being attached to a deployment actuator and said distal portion being attached to said marker element, wherein actuation of said deployment actuator is transmitted from the proximal portion of the connector to the distal portion thereof to cause release and deployment of said marker element.

14. A device as recited in claim 13, and further comprising a predetermined failure point in the distal region of said deployment actuator connector, wherein once the distal region of said member is positioned at said selected tissue location, the deployment actuator may be actuated to pull the marker element against the distal region of said member, said member distal region being adapted to function as a forming die to cause the marker element to bend until it encounters a stop designed into said member distal region, such that the marker element is reconfigured to a desired shape, the proximal portion of said ^{connector} ~~connecting means~~ being adapted to be severed from the distal portion at said predetermined failure point upon the further actuation of said deployment actuator after abutment of the marker element against said stop, thereby releasing and implanting said marker element.

15. A device as recited in claim 1, and further comprising a plurality of marker elements adapted to assume a plurality of shapes, wherein each shape denotes a different selected tissue location or event.

16. A device as recited in claim 1, wherein said device is adapted to be employed in combination with a medical instrument which transports said device to said selected tissue location responsive to positional control by a guidance system.

17. A device as recited in claim 16, wherein said medical instrument draws a vacuum to isolate and retain tissue at the selected location and said marking device is adapted to deploy said marker element into said retained tissue.

18. A device as recited in claim 38, wherein said tube lumen is adapted to receive a plurality of marker elements.

19. A marker element for marking tissue within a human body to identify a selected location for a diagnostic or therapeutic procedure, said marker element being comprised of a biocompatible and implantable material and being deployable to the selected tissue location percutaneously by a delivery apparatus, such that the marker element becomes implanted in said tissue.

20. A marker element as recited in claim 19, wherein said marker element is formed into a predetermined shape upon exiting said delivery apparatus and becoming implanted in said tissue.

21. A marker element as recited in claim 19, wherein said marker element includes sharp edges or protrusions adapted to pierce tissue and thereby become anchored therein.

22. A marker element as recited in claim 19, wherein said marker element comprises a radiopaque material.

2025-06-06 10:00:00

B

5

23. A marker element as recited in claim 22, wherein said material is metallic.

24. A marker element as recited in claim 22, wherein said material is non-metallic.

25. A marker element as recited in claim 19, wherein said marker element comprises a plurality of attachment members, each of which has a tip end adapted for implantation into said tissue.

26. A marker element as recited in claim 25, wherein said plurality of attachment members are spring loaded such that they expand, the expansion functioning to implant said plurality of attachment members into said tissue.

27. A marker element as recited in claim 19, wherein said marker element comprises a spring which is adapted to expand upon deployment from said delivery apparatus, the expansion functioning to implant the marker element into said tissue.

28. A marker element as recited in claim 19, wherein said tissue location is a lesion in a human breast.

29. A method for permanently marking tissue in a human body to identify a selected location for a diagnostic or therapeutic procedure, the method comprising:

a) manipulating a delivery apparatus having a distal region to a position wherein the apparatus extends through the human body and the distal region is at the selected location, and

b) deploying a marker element into said selected tissue location, such that it becomes substantially permanently implanted in the tissue.

30. The method as recited in claim 29, wherein said deployment step includes the step of forming and releasing said marker element.

31. The method as recited in claim 29, wherein said deployment step includes the release of said marker element from the distal region of said delivery apparatus.

32. The method as recited in claim 29, wherein said deployment step includes the step of drawing tissue from said selected tissue location into a tissue receiving port in said delivery apparatus, and deploying said marker element into the tissue in said tissue receiving port.

33. The method as recited in claim 29, wherein said deployment step includes the step of actuating a deployment actuator to form and release said marker element.

34. The method as recited in claim 29, wherein said deployment step includes the step of actuating a mechanism to release said marker element from said distal region.

add B2
add E3